

Formulary Policies a Battleground In HHS Proposal on Nondiscrimination

Are Tiering and Cost Sharing Civil Rights Issues?

Stephen Barlas

Is the federal government once more on the cusp of tweaking rules for marketplace, Medicare, Medicaid, and other federally funded health programs with regard to formularies and P&T committees? It could happen. Patient advocacy groups and drug companies are pushing for more aggressive requirements with regard to things such as pharmaceutical cost sharing and utilization management techniques. Health insurers and pharmacy benefit managers (PBMs) are fighting against that.

The political venue for this is the proposed rule the Department of Health and Human Services (HHS) issued last September on Section 1557 of the Patient Protection and Affordable Care Act.^{1,2} It bans discrimination in health care and jumps off from previous nondiscrimination laws in the areas of voting rights, education, access to facilities, and much else. Those earlier, existing laws prohibit discrimination on the basis of race, color, national origin, sex, age, or disability. However, the upcoming nondiscrimination rule from the HHS has prompted concerns from various quarters for a couple of reasons. The proposed rule extends the definition of sex discrimination to include discrimination based on gender identity. It will also require hospitals, health plans, physician offices, pharmacies, state and local programs, and others to do some things they currently do not do under existing civil rights laws in terms of notification, training, and translation services for patients. The HHS estimates the industry-wide cost at \$558 million over a two-year period.

Interestingly, the proposed rule nowhere mentions the application of Section 1557 to “formularies.” That word doesn’t appear anywhere in the proposed rule’s text. Neither does “P&T committee.” The proposal concerns itself with such issues as access to facilities for the disabled, translation services for non-English speakers, and how health plans, hospitals, and other providers must describe and provide medical services for transgender and gay individuals. That said, many, if not most, of the 2,000-plus comments that arrived on the HHS doorstep in the wake of the proposed rule raise, among other concerns, the issue of formularies, either pressing for extension of Section 1557 to formularies or opposing it.

“It is our understanding that the department continues to face pressure from several patient advocacy groups and pharmaceutical manufacturers to prevent or severely restrict application of clinically based utilization management and formulary design processes under a pretext that use of step therapy, tiering, or other such tools are in fact discriminatory practices in and of themselves,” says Jonah Houts, Vice President of Corporate Government Affairs for Express Scripts, Inc.

Lisa Joldersma, Vice President of Policy and Research for Pharmaceutical Research and Manufacturers of America (PhRMA), says, “The evidence on today’s formulary landscape clearly indicates that too often plan formularies have designs that discourage individuals with certain disabilities from enrolling in their plans. Across HIV classes, certain cancer classes, and medicines that treat multiple sclerosis, many marketplace plans are putting all medicines, brand and generic, on the highest cost-sharing tier.”



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Drug Access in Federal Health Plans Has Long Been a Controversy

The issue of formulary “discrimination” has come up over the past few years in the context of marketplace and Medicare Part D/Medicare Advantage guidance—which has no legal standing—and proposed rules dealing mostly with appeals to denials of particular drugs. Health plans have argued against the Centers for Medicare and Medicaid Services (CMS) addressing tiering and cost-sharing requirements and are doing so again with regard to the proposed 1557 rule.

“We recommend revising the rule to provide specific safe harbors with respect to pharmacy benefits, so that formularies designed by a pharmacy and therapeutics committee would not be considered discriminatory,” says David Schwartz, Head of Global Policy for Cigna Federal Affairs. “CMS has already issued detailed rules on drug formularies and the department should defer to CMS’s rules to ensure uniform, clinically based, sound formulary decisions.”

Again, the only rules the CMS has issued on formularies deal with time frames for health plans to respond to appeals of denials of specific medications, mandating that all drugs be provided in certain “protected classes” of drugs, and, with regard to marketplace formularies, establishing the standard for which drug classes must be made available.

That is not to say the CMS and the HHS are not worried about drug cost-sharing policies adopted by health plans and how P&T committees arrive at those formularies. The CMS has already been doing an outlier analysis that assesses marketplace plans’ cost-sharing requirements. Year 2015 and 2016 “Letters to Issuers in the Federally-facilitated Marketplaces” sent by the CMS promised to perform “an outlier analysis on QHP [qualified health plan] cost sharing (e.g., co-payments and co-insurance) as part of the QHP certification application process.” Both letters go on to say that “outliers may be given the opportunity to modify cost sharing for certain benefits if CMS determines that the cost-sharing structure of the plan that was submitted for certification could have the effect of discouraging the enrollment of individuals with significant health needs.” QHPs are required to ensure nondiscrimination

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in each of the 10 categories of essential health benefits they must provide, one of which is prescription drugs. In that vein, the 2015 letter said, “CMS intends to review plans that are outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular category and class. We encourage states performing plan management functions in an FFM [federally facilitated marketplace] to implement this type of review.”^{3,4}

The 2017 draft “letter” went further. It said: “CMS is also concerned about adverse tiering, which occurs when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high-cost medical condition to a high cost-sharing tier. Since adverse tiering is potentially discriminatory, this review may examine the tier placement of prescription drugs to determine whether QHPs are also consistently placing drugs used to treat these medical conditions on a high cost-sharing tier.”⁵

These “letters,” whether to marketplace health plan or Part D providers, are advisory. They do not have the force of law. Moreover, while the CMS has apparently been applying outlier analyses to federally regulated formularies, the agency has never published the results of these, nor published a list, for example, of “bad practices,” which might guide health plans.

Timothy Jost, Emeritus Professor at Washington and Lee University, who has written widely on federal health policy, notes that the CMS and states review marketplace and Part D plans annually and, if they feel an individual plan uses drug tiering in a discriminatory fashion, they can kick the plan back for remediation. Jost adds that where states review marketplace plans, “they are all over the lot” in how they enforce marketplace essential health benefit standards as they apply to pharmaceutical access.

The CMS has, however, established federal policies related to P&T committees operating in Medicare Part D plans. There is some concern among PBMs and health insurers that the HHS might extend those policies, or even enrich them, in the context of a final Section 1557 rule. “As we share the department’s priorities in preventing discriminatory practices from occurring in health care, our concern focuses on whether any future proposals affecting the P&T committee process will enhance the protections already available to patients, or add only complexity and costs to plan compliance at the expense of patients and sponsors,” says Express Script’s Houts.

First in its Call Letter for 2015 and again in its 2016 letter for Medicare Part D plans, the HHS laid out refinements of “independence” requirements for P&T committees. A minimum of two members on each P&T committee must be independent from the plan sponsor and drug manufacturers, but not the PBM. The 2016 letter, for example, required that the sponsor’s P&T committee clearly articulate and document processes to determine that members who are supposed to be independent are indeed independent, and committees must have a policy to manage recusals due to conflicts. Those processes must be enforced by “an objective party,” which may be a representative of the PBM—as long as that representative is not also a member of the sponsor’s P&T committee.

Jost believes the HHS may have its work cut out for it in applying Section 1557 to formularies and P&T committees. He believes nondiscrimination in the context of disabilities, as is

the case with Section 1557, is different than nondiscrimination with regard to health status, which is what the marketplace plans are charged with avoiding. Also, the proposed rule doesn’t raise the issue of discriminatory formularies. “The HHS is limited in going off in a new direction if that direction is not mentioned in the proposed rule,” Jost explains. “But it could issue a final rule and another proposed rule dealing with formulary discrimination.”

Allyson Funk, Senior Director of Communications at PhRMA, thinks the HHS could and should apply Section 1557 to formularies. “We would like to see additional clarification in the final rule which would be a logical outgrowth of the proposed rule’s prohibition on ‘benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy, or other health-related coverage,’” she says.

Expansion of Current Nondiscrimination Policies ... or Not

Complaints about current discrimination have been loud from transgender advocacy groups, who have been among those pressing for formulary expansion provisions. But they have been equally concerned about availability of medical services. In the proposed rule, the HHS said “coverage for medically appropriate health services must be made available on the same terms for all individuals, regardless of sex assigned at birth, gender identity, or recorded gender.” It used pelvic exams as an example. They cannot be denied for an individual for whom a pelvic exam is medically appropriate based on the fact that the individual either identifies as a transgender man or is enrolled in the health plan as a man.

The HHS goes on to say that coverage cannot be denied for gender transition. If, for example, a health plan or state Medicaid agency denies a claim for coverage of a hysterectomy that a patient’s provider says is medically necessary to treat gender dysphoria, the HHS Office of Civil Rights (OCR), if it gets a complaint, will evaluate the extent of the plan’s coverage of hysterectomies under other circumstances. The OCR will also carefully scrutinize whether the covered entity’s explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination. But the HHS makes it clear that a final rule will not require covered entities to cover any particular procedure or treatment for transition-related care; nor do they preclude a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a non-discriminatory manner.

However, the HHS proposed policy on transgender access to services is not totally clear to everyone. “As it is currently worded, the proposed rule suggests that clinicians who recommend screening tests and similar services usually performed only on those of the individual’s birth gender may be acting in a prohibited manner. We do not believe this was HHS’s intention,” says Ashley Thompson, Acting Senior Executive of Policy at the American Hospital Association.

Nondiscrimination Beyond Medical Services

Whatever the HHS decides in the final rule, any edicts will affect not just the kinds of services that hospitals, physicians, and pharmacies will have to provide, but potentially

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even the continuation of certain federally funded health programs. For example, Unite for Reproductive & Gender Equity (URGE) wants some federally funded health programs to be canceled because they do not square with Section 1557. It cites abstinence-only-until-marriage (AOUM) programs currently funded by HHS and administered by the Family and Youth Services Bureau within the Administration for Children and Families. “AOUM programs are inherently discriminatory against LGBTQ [lesbian, gay, bisexual, transgender, and queer] young people,” says URGE. According to the Society for Adolescent Health and Medicine, “in addition to abstinence-only classes being unlikely to meet the health needs of LGBTQ youth, as they largely ignore issues surrounding homosexuality, they often stigmatize homosexuality as deviant and unnatural behavior.”

But insurance companies worry about how antidiscrimination laws newly applied to transgender individuals might adversely affect them. According to Cigna’s Schwartz:

While Cigna supports measures of diversity and inclusivity, there are operational procedures today that may be construed as violating Section 1557, albeit unintentionally. Claim adjudication programming helps to protect against abusive billing practices by using edits, such as gender identifiers, to identify an anomaly; such as a male gender indicator on a claim for an annual well-woman exam or a female gender edit for a prostate exam. Medical claim adjudication procedures as well as pharmacy claim adjudication procedures would be impacted by the proposed rule. Furthermore, based on the language in the proposed rule, it is unclear if a gender question on an application is even acceptable or if it could be construed as sex stereotyping.

Disability groups are concerned that Section 1557 regulations would allow private entities to essentially decide for themselves when their provider network is “readily accessible” to people with disabilities. “A large for-profit insurance carrier could arbitrarily decide that, among the great majority of its providers who operate in existing facilities, only 10% need to be physically accessible or have accessible equipment,” says the Consortium for Citizens with Disabilities (CCD). “Moreover those accessible providers could be clustered together in some central location, and whenever a member calls member services and mentions the need for accessibility, that member will be actively directed toward ‘the accessible provider offices.’”

Groups representing the deaf also cite shortcomings in interpretation services currently available and thus the need for Section 1557 regulations to specify more rigorous requirements than those in the current nondiscrimination laws. “Too often, patients who use ASL [American Sign Language] are denied access to health care because most providers do not provide qualified ASL interpreters,” reports the National Association of the Deaf. “Furthermore, the department should emphasize that by no means should family members act as interpreter for the deaf or hard of hearing patient. Many health care entities mistakenly believe that it is perfectly acceptable to utilize family members as interpreters. In fact, the website for the American Medical Association states that ‘qualified interpreters may include: family members or friends,’ which demonstrates an incorrect understanding of the regulatory definition for a ‘qualified interpreter’ (QI).”

Implications for Pharmacies and Hospitals

As opposed to formularies, the Section 1557 proposed rule does have specific requirements for brick-and-mortar health facilities covered by the upcoming rule. They would have to notify patients that they offer auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities. The notice would need to be translated into at least 15 different languages.

Another requirement would force hospitals, pharmacies, and health plans to provide language assistance services, including interpreter and translation services for non-English speakers and similar services for the deaf. Those have to be available at the point a service is being provided.

In the case of an individual with limited English proficiency, the covered entity must offer that individual an on-the-spot, qualified, oral interpreter, who generally may not be a family member and almost never a child. There is an exception which is narrow in scope. Interpreters at a remote location can be used.

The American Pharmacists Association (APhA) is making the argument that pharmacies shouldn’t be covered (though hospital pharmacies, as part of a hospital’s corporate structure, would be) to the same extent as other “covered providers.” Retail pharmacies do not get marketplace, Medicare, or Medicaid reimbursement, though, in the latter case, they do receive dispensing fees. The APhA believes the amount of federal financial assistance a covered entity receives for a particular service should be a determinative or heavily weighted factor when imposing requirements related to Section 1557 and in OCR’s determinations related to nondiscrimination claims. Scaling down the requirements on pharmacies is important, in the APhA’s view, because of the mandates related to things such as translation services for customers, to give one example.

“APhA is very concerned that OCR requires the notice to include a statement that the covered entity provides auxiliary aid and services and language assistance services, free of charge, and makes no mention of the inclusion of a disclaimer or caveat related to the fact that the provision of services is balanced against the burden placed on the entity,” says Thomas E. Menighan, Executive Vice President and CEO of APhA. “Such a notice basically provides a guarantee of the services and fails to factor in the burden on the entity which OCR claims to consider.”

Pharmacies currently providing translation services (written or oral) have noted that costs may be considerable. Additionally, written translation services are effective only if the patient is literate. Pharmacists may also have difficulty identifying which language the patient is speaking, further exacerbating the difficulty of connecting the patient to a qualified QI. Even if a QI can be found, those without the appropriate medical training may be unable to accurately translate technical information, making such services less meaningful to patients and a source of potential liability for pharmacies.

At least hospitals and pharmacies know what they are in for when the Section 1557 final rule is published. The rule’s impact on QHP and Part D formularies is harder to predict. The political pressure has been building on the HHS to take a stronger stand on tiering and associated practices. But given the very recent disclosures of the money major health insur-

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ers are losing on their marketplace plans, it may be hard to justify putting out of reach what the plans have long argued are major, justifiable cost-control practices.

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